323 U.S. #2

ARN-BAN

In the

Supreme Court of the United States.

OCTOBER TERM, 1944.

No. 301

ARNER COMPANY, INC., ET AL.,
Respondents, Appellants, Petitioners,

v.

UNITED STATES OF AMERICA,
Libellant, Appellee, Respondent.

PETITION FOR WRIT OF CERTIORARI

AND

BRIEF IN SUPPORT OF SAME.

CLINTON ROBB,
HERBERT S. AVERY,
Solicitors for Appellants.

L. H. LANE COMPANY, LAW PRINTERS, 221 HIGH ST., BOSTON, MASS.

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RESPONDENTS, APPELLANTS, PETITIONERS,
v.
UNITED STATES OF AMERICA,
LIBELLANT, APPELLEE, RESPONDENT.

PETITION FOR WRIT OF CERTIORARI.

To the Honorable the Chief Justice of the Supreme Court of the United States and the Associate Justices Thereof.

The petitioners, Arner Company, Inc., and Paul Case, respectfully request that a Writ of Certiorari may issue to review the judgment of the United States Circuit Court of Appeals for the First Circuit in the case of Arner Company, Inc., et al. *v.* United States of America, 142 Fed. (2d) (R., p. 20), rendered on May 4, 1944, which affirmed the judgment of the District Court entered on April 6, 1943 (R., pp. 7–9).

JURISDICTION.

The jurisdiction of this Court is invoked under the Act of Feb. 13, 1925, Chapter 229, Sec. 1 to 43, Statutes 938, U.S. Code, Title 28, Sec. 347.

This petition was filed within the three months from May 4, 1944, the date of entry of the judgment of the Circuit

Court of Appeals as required by Section 8 of the Act of Feb. 13, 1925, *supra* (U.S. Code, Title 28, Sec. 350).

Notice of the filing of this petition together with a copy of the petition, printed record and supporting brief, has been duly served by the petitioners upon counsel for the respondent and due proof of such service filed with the clerk, as required by Rule 38 of this Court.

THE QUESTIONS PRESENTED.

The questions presented are of first impression. There is a conflict of decisions between the Circuit Court of Appeals: —Fourth Circuit—*United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022; Sixth Circuit—*Strong, Cobb Co.* v. *United States*, 103 Fed. (2d) 671—and the present case; which should be set at rest.

The questions are important in order to avoid unwarranted interference with certain legitimate commercial operations, such as the canning of food at branch canneries and delivery to a central plant for labeling, or *the bulk shipment of food or drugs for processing and repacking before distribution to consumers.* See Senate Report No. 493, Seventy-third Congress, Second Session 1934, p. 9, accompanying S-2800, one of the bills leading to the enactment of the present law.

Five fundamental questions are involved:

First: Does the Food & Drug Act, so-called, of 1938, require the labeling under the provisions of Section 502 of bulk packages which are to be shipped to a processing or labeling plant and not intended for distribution to the ultimate consumer?

Second: Does Section 503 of the Act require bulk packages of drugs which are to be processed, repacked and labeled before being distributed to the consumer to be exempted from labeling requirements?

Third: Is the Administrator authorized and permitted

under the Act to promulgate regulations requiring the shipper of bulk packages of drugs which are to be processed, repacked and labeled before being distributed to the consumer, to obtain from the operator of the repacking establishment a guaranteed description of the exact form and contents of label to be attached to the retail package?

FOURTH: Does the guarantee of the operator of the repacking establishment to the shipper of the bulk package that the drugs are not adulterated or misbranded within the meaning of the Food & Drug Act constitute a sufficient compliance with the statutes involved?

FIFTH: Do the regulations established by the administrator under Section 503 (a) (1) (2), exceed the authority granted by the statute?

STATUTES INVOLVED.

This case calls for an interpretation of the provisions of the Food & Drug Act, so-called, of 1938, particularly Section 201 (k) (l) (m), (21 U.S.C.A. 321), Sections 301 (a) (21 U.S.C.A. 331), Section 502 (c) (f) (21 U.S.C.A. 352) and Section 503 (a) (21 U.S.C.A. 353) and the regulations promulgated under Section 503 (a) (1) (2).

Section 201 has the following pertinent provisions:

> (k) "The term 'label' means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."
>
> (l) "The term 'immediate container' does not include package liner.

(m) "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such articles."

Pertinent provisions of Section 301 are as follows:

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetics that is adulterated or misbranded."

Pertinent provisions of Section 502 are as follows:

"(e) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood *by the ordinary individual under customary conditions of purchase and use* and (italics ours)

(f) unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe doses or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is *not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirements.*" (Italics ours.)

"Such drug or device shall deem to be misbranded."

The pertinent provisions of Section 503 are as follows:

(a) "The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs or devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishments."

The pertinent provisions of the regulations under Section 503 (a) are as follows:

(a) "Except as provided by paragraph (b) and (c) of this Regulation, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce, and the time of holding in such establishment, from compliance with the labeling and packaging requirements of Section 501 (c) and 502 (c) (d) (e) (f) and (g) of the Act if

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post office address of such person, and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if

such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person or such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the agency who requests it."

(b) "An exemption of a shipment or delivery of a drug or device under clause (1) of paragraph (a) of this Regulation shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void *ab initio* if the drug or device comprising such shipment, delivery, or parts is adulterated or misbranded within the meaning of the Act when so removed."

STATEMENT OF THE CASE.

This is a libel for the condemnation of certain drugs alleged to have been misbranded.

The drugs were seized by the United States Marshal at the plant of Paul Case in Brockton, Massachusetts, while in the bulk package in which they had been shipped from Buffalo, New York. The package was labeled "Special Formula No. 2" and contained the following statement:

> "The product contained herein must be packaged and labeled at point of destination before sale." See R., p. 13, Exhibit (A).

The drugs were to be repackaged by Paul Case for the retail trade and were not, at the time of seizure, in a package intended for the consumer.

It was alleged that the label upon the package which was seized was not such a label as was required under the Food &

Drug Act because it did not contain the required statement of the ingredients of the drugs and contained no statement warning against habit-forming qualities.

The appellants denied that the package seized was misbranded and asserted that it was exempt from the labeling requirements of the Statute as it was not the immediate container of the article intended for consumption by the public. The case was presented on an Agreed Statement of Facts, the District Court, in an opinion, held that the package was misbranded and ordered its condemnation and the appellants duly appealed from such decree of condemnation.

The libel referred to two packages containing drugs, there was actually seized one package or drum containing about 40,000 tablets of "Special Formula No. 2."

The drum when seized was on the premises of the appellant, Paul Case, in Brockton, Massachusetts. It was the original bulk package container in which had been shipped from the plant of the Arner Company in Buffalo, New York, certain pills described as manufactured according to "Special Formula No. 2."

Special Formula No. 2 was the property of the appellant, Paul Case, a trade secret. According to this formula there were manufactured by the appellant, Arner Company, certain tablets under an agreement with the appellant, Paul Case, which tablets were shipped from the plant of the appellant, Arner Company, Buffalo, New York, F.O.B., to the plant of the appellant, Paul Case, Brockton, Massachusetts, there to be repackaged by the appellant, Paul Case, for distribution to the consuming public.

The drum in which the tablets were shipped contained a label describing the contents as "Special Formula No. 2", as per Exhibit "A", attached to Agreed Statement of Facts (R., p. 13).

There is no question raised as to the adulteration of the tablets and no question raised as to the improper labeling of

the retail package or immediate container of the article intended for the consumption by the public.

As a part of the agreement for manufacture of the tablets entered into between the appellant, Case and the appellant, Arner Company, there was the following letter: (See Exhibit "C" attached to Agreed Statement of Facts, R., p. 15), which contained thereon the receipt acknowledgment of the Arner Company as follows:

> "To the Arner Company, Inc., Pharmaceutical Chemists, Buffalo, New York. I, the undersigned, Paul Case, whose address is 33 Hamilton St., Brockton, in the State of Massachusetts, do hereby guarantee the Arner Company, Inc., of Buffalo, New York, that each shipment or other delivery hereinafter made of the drugs known or designed as my Formula No. 1 and Formula No. 2, is not adulterated or misbranded as of the date of such shipment or delivery, within the meaning of the Federal Drug, Food & Cosmetic Act, and is not an article which may not, under the provisions of Section 505 of the Act, be introduced into commerce. (signed) Paul Case, Owner."
>
> Received Arner Company, Inc., April 29, 1939.

STATEMENT OF POINTS RELIED UPON IN APPEAL TO THE CIRCUIT COURT OF APPEALS.

I. The Food & Drug Act, so-called, Section 502 (c) (2), Section 502 (f) (1), Section 502 (f), do not apply to the bulk package shipment herein involved (21 U.S.C.A. 352), see Definition Labels and labeling, Section 201 (k) (m) (l) in (21 U.S.C.A. 321).

II. The bulk package herein involved is specially exempted under Section 503 (a) and Regulation (a) (1), (21 U.S.C.A. 353).

III. If not specially exempted under Section 503 (a), (21 U.S.C.A. 353), Regulation (a) (1), it is exempted under

Section 503 (a) by reason of sufficient compliance with said section by the agreement entered into between Paul Case and the Arner Company (Exhibit "C", p. 15).

IV. The regulations established by the Federal Security Administrator, so far as they may be held to apply to the bulk package herein involved, exceed the power granted under the statute and the intent of Congress in passing such statute and are wholly unwarranted and unnecessary as applying to the case at bar.

REASONS SUBMITTED FOR ALLOWANCE OF THIS PETITION.

As stated by the District Court judge in his decision, R., p. 8, the last paragraph, "The case is one of first impression."

The reasoning and decision rendered by the Circuit Court of Appeals is contrary to the reasoning and decision of the Circuit Court of Appeals of the Fourth Circuit in the case of *United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022, contrary to the reasoning and decision of the United States Supreme Court in *McDermott* v. *Wisconsin*, 228 U.S. 116 and is such a marked departure from the reasoning and decision above quoted as to require a determination by this court to set at rest the conflict.

The questions presented involve an important part of certain legitimate commercial operations carried on extensively not only by the respondent, Arner Company, but by large manufacturers of drugs and chemical products throughout the country and materially affects their methods of operation.

The commercial operations involved were of such importance as to require special attention by Congress in the course of the passage of the act involved and to require special legislation therewith and requires judicial determination to set at rest the substantial doubts raised by this litigation and this libel.

Cases relied upon by the Circuit Court of Appeals to sustain their decisions are cases involving not misbranding of drugs but the adulteration. The Supreme Court has heretofore held that there was a distinct difference between the application of the statute to misbranding and to adulteration and before this distinction is obliterated an interpretation of the present act as to the points involved is required.

PRAYER FOR WRIT.

Wherefore, your petitioners, by their undersigned counsel, respectfully pray that a Writ of Certiorari be issued out of and under the seal of this Honorable Court, directed to the United States Circuit Court of Appeals for the First Circuit, commanding that court to send to this court for its review and determination, on a day certain to be therein named, a full and complete transcript of the record and also pleadings in the case entitled Arner Company, Inc., et al., Respondents, Appellants, *v.* United States of America, Libellant, Appellee, being designated and numbered on its Docket October Term, 1942, No. 3928 and that the said judgment of the Circuit Court of Appeals may be reviewed by this Honorable Court, to the end that your petitioners may have the relief therein prayed for and such other and further relief in the premises as to this Honorable Court may seem just and proper.

Respectfully submitted,

ARNER COMPANY, INC. AND PAUL CASE,
by their Attorneys,
HERBERT S. AVERY,
177 State St., Boston, Mass.

CLINTON ROBB,
Transportation Building, Washington, D. C.

CERTIFICATE.

I hereby certify that Clinton Robb of Washington, D. C., and I are counsel for the petitioners herein, Arner Company, Inc., and Paul Case; that in accordance with the request of said petitioners the within Petition has been presented; that the allegations contained in said Petition are true, to the best of my knowledge and belief; and that said Petition is, in my opinion, well founded in law and in fact and should be granted.

HERBERT S. AVERY.

COMMONWEALTH OF MASSACHUSETTS.

COUNTY OF SUFFOLK, ss., BOSTON, July 15, 1944.

Then personally appeared Herbert S. Avery of Boston, Massachusetts, and made oath that he caused the foregoing Petition to be prepared and signed the same and that the same is prepared with the consent of and in accordance with the request of the petitioners named therein and that the allegations contained in said Petition are true to the best of his knowledge and belief.

Before me,

A. L. KAPLAN,

[SEAL] *Notary Public.*

My commission expires March 31, 1950.

BRIEF IN SUPPORT OF PETITION.

In support of the allowance of the Petition, the following is respectfully submitted:

ARGUMENTS AND AUTHORITIES.

I.

THE COURSE OF REASONING AND DECISION RENDERED BY THE CIRCUIT COURT OF APPEALS IN THE CASE AT BAR AS IT RELATES TO THE APPLICATION OF THE LABELING REQUIREMENTS OF THE STATUTE TO BULK PACKAGES IS CONTRARY AND IN CONFLICT WITH THE DECISIONS OF THIS HONORABLE COURT.

The Federal Food, Drug & Cosmetic Act, so-called, was enacted June 25, 1938, to take effect twelve months thereafter and upon its taking effect the previous Food & Drug Act of June 30, 1906, became repealed.

Section 201 (k) (l) (m), (21 U.S.C.A. 321) contains the following definition:

> (k) "The term 'label' means a display of written, printed or graphic matter upon the immediate container of any article; and the requirements made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, there be, of the retail package of such article, or is easily legible through the outside container or wrapper."
>
> (l) "The term 'immediate container' does not include package liner.
>
> (m) "The term 'labeling' means all labels and other written, printed or graphic matter (1) upon any article

or any of its containers or wrappers or (2) accompanying such article."

The primary and fundamental purpose of the so-called Food & Drug Act and similar food and drug regulations is to protect the consuming public from harm or injury through use of improper or harmful drugs and foods.

The requirements as to labeling and branding are designed to convey to the consumer all necessary information and knowledge so that he may use foods and drugs safely. The consumer is the person to be protected and benefited and all requirements as to labeling must be construed with reasonable attainment of that objective in view. This has been so held in the case of *McDermott* v. *Wisconsin,* 228 U.S. 116, 130, 131, where the court said,

> "The word 'package' or its equivalent expressions, as used by Congress in Sections 7 and 8, in defining what shall constitute adulteration and what shall constitute misbranding within the meaning of the Act, merely refers to the immediate container of the article which is intended for consumption by the public, there can be no question:—Within the limitations of its right to regulate interstate commerce, Congress manifestly is aiming at the contents of a package as it shall reach the consumer, for whose protection the Act was primarily passed, and it is the branding upon the package which contains the article intended for consumption itself which is the subject matter of regulation.—The object of the Statute is to prevent the misuse of the facilities of interstate commerce in conveying to and placing before the consumer misbranded and adulterated articles of medicine or food, and in order that its protection may be afforded to those who are intended to receive its benefits, the brand regulated must be upon the packages intended to reach the purchaser."

Furthermore, it must be assumed that Congress was fully familiar with these decisions and with the attempt of the government under previous laws to extend the labeling requirements to bulk packages, such as the one in question in this case at bar. It is also evident that Congress, considering the provisions of the act in question, gave considerable attention to the matter of shipment in bulk packages recognizing it as an important part of legitimate commercial operations which ought not to be unwarrantably interfered with so long as the main purpose of the act was attained, that is, the protection of the consuming public. In this connection, see Senate Report No. 493, Seventy-third Congress, Second Session, 1934, p. 9, accompanying S-2800.

It will be observed that the wording of the Act of 1906 gave far more support to the government in its contention that bulk shipments, though not made nor intended for sale until repackaged and labeled, require the same labels necessary for retail packages intended for purchasers or users, than can be found for the same contention now made under the Act of 1938.

Under the original act, see Title 28, U.S.C.A., Sec. 9,

> "misbranded; meaning and application. the term 'misbranded' as used in Sections 1 to 15, inclusive, of this Title shall apply to all drugs or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such package, or the ingredients or substances contained therein, which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to state, territory or country in which it is manufactured or produced."

In the present act the definition of "label" and "labeling" not found in the earlier act, makes reasonably clear

that Congress, in providing the labeling requirements in Section 502, (21 U.S.C.A. 352), referred to in the pending libel, had in mind the retail package which is intended for and goes to the public.

Thus, where the government failed under the Act of 1906 in a persistent effort to extend to the bulk package not intended for sale to consumers or users the label requirements applicable to retail packages sold to the public, Congress certainly was in a position to have made certain that the act should extend to such bulk packages if it had deemed it advisable or necessary that it do so.

On the contrary, however, as will be more fully developed, Congress indicated more clearly than before its intention that the labeling requirements should apply to the retail package and not to bulk packages which were not intended to reach the consumer.

Section 201 (k), (21 U.S.C.A. 321), provides as follows:

> "The term 'label' means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement by or under the authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper."

Obviously, the label which is defined and required is the one appearing on the retail package. Under the definition the label on the bulk package could contain all of the information contended for by the government and be as expressive as the most exact prosecutor could require and yet if the label on the retail package did not comply with the requirements, the goods would be deemed to be improperly

labeled from the very start of their introduction into interstate commerce and could be seized. Thus clearly, it is the label on the retail package that determines the test as to whether there is improper labeling.

There can be no contention made in this case that the labeling on the retail package did not meet the requirements of the statute.

Thus, we may assume, for the purposes of this case, that these drugs, when they reached the consuming public, were properly labeled and the primary object of the statute attained.

This point is further emphasized when we consider the language of Section 503 (a), (21 U.S.C.A. 353), providing as follows:

> "The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirements of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at the establishments other than those where originally processed and packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishments."

Placing these two provisions side by side, it is perfectly apparent first, that Congress in defining label defined it clearly as the label appearing on the retail package and then, in order to be sure that there could be no misunderstanding of the intent of the definition and the statute, followed with the provision that bulk packages such as the one in the case at bar should be exempt from the labeling requirements provided the labeling on the retail package met the requirements.

Not only do we have the provisions of the statute already

cited, which show the clear intent of Congress that the bulk package is not to be affected by the statute under the circumstances of the case at bar, but in addition to that we have the provisions of Section 502 (c) and Section 502 (f) which undertake to define the conditions under which a drug or device shall be deemed misbranded. (c) provides that the labeling shall be "in such terms as to render it likely to be read and understood by the *ordinary individual under customary conditions of purchase and use,*" (italics ours) and (f) the provision, "provided that where any requirement of clause (1) of this paragraph, as applied to any drug or device, *is not necessary for the protection of the public health* (italics ours), the Administrator *shall* promulgate regulations exempting such drug or device from such requirements."

Obviously, the shipment of drugs in a bulk package from the manufacturer to the processor who is to repackage and label and particularly drugs which are made from a formula provided by the processor who has full knowledge of the contents and effect of the formula, perhaps an even greater knowledge of the effect of the formula upon the retail public than would the manufacturer, would not in any sense involve the public health and would in no way affect the public until such time as those drugs were processed, repackaged and labeled and shipped to the retail consumer.

The suggestion of the Circut Court of Appeals that the labeling of the bulk package would be of assistance to the federal authorities in the administration of the act is far fetched from any practical view of the situation because, in the first instance, it would aid the federal authorities only to the extent of determining adulteration and could have no bearing on the question of the misbranding to which the statute is directed, and, in the matter of adulteration, the simple determination of whether the drugs are adulterated, that is, whether they do not comply with the formula on which they are manufactured, would be by the analysis of

the drug and the comparison of that analysis with the formula; to which formula the federal authorities would have ready access under the provisions of the statute. In other words, to determine whether the drugs were adulterated the Administrator must determine whether their component elements meet the requirements of the formula under which they are manufactured. To determine whether they are misbranded or not the Administrator must determine whether the drugs manufactured according to formula are properly labeled on the package which goes to the ultimate consumer. Therefore, the label on the package containing the bulk goods shipped from the manufacturer to the reprocessing plant can be of no assistance to the administrator, either in the determination as to adulteration or in the determination as to misbranding.

A careful analysis of the object of the statute clearly shows that the reasoning of the Circuit Court of Appeals, that the branding or labeling on the bulk package would be of assistance in enabling the federal authorities to enforce the statute, has no statutory support.

This view of the statute and the regulations thereon must further be clearly discarded when we consider the direct provisions of the statute requiring exemptions of the bulk packages, such as herein involved, from the labeling requirements of the statute.

It is perfectly clear that Congress did not intend to interfere with that large element of legitimate commerce, namely, the shipping in bulk packages of food and drugs from manufacturing plants to processing plants, even though those shipments were in interstate commerce, so long as the articles in question did not reach the consuming public, for whose protection the legislation was designed, in either an adulterated or a misbranded condition.

The label on the bulk package addressed to Paul Case, if it had contained the full directions as to the retail labeling,

could not have been of any assistance to Paul Case because he knew the contents of the formula, he knew of what benefit the drugs could be to the ultimate consumer. There could be no assistance to him nor protection to him in having such a label upon the package. As has already been pointed out, such a label on the package could of course have been no benefit to the public and could not have been of any assistance to the federal authorities in the enforcement of the act.

That the bulk package is to be treated and considered under a different category than the retail package, and that the contention of the respondent in the present case is sound, is well established by the decision of the District Court in the case of *United States* v. *65 Casks Liquid Extract,* 170 Fed. 449, supported on appeal to the Circuit Court of Appeals by *United States* v. *Knowlton Danderine Co.,* 175 Fed. 1022 and affirmed in the case of *Dr. J. L. Stephens Co.* v. *United States,* 203 Fed. 817 and cited with approval in the case of *Hipolite Egg Co.* v. *United States,* 220 U.S. 45.

In the first mentioned case the trial court said in part as follows:

> "It is apparent that the formula of the preparation is a secret; that Parke Davis Co. were not the owners of this formula, but only the manufacturing agents, under a contract, of the owner, the Danderine Co., and only acted as agents of the owner in directing such shipment to the owner itself of its own property; that such owner did not, 'having so received' such product, either 'deliver, in the original unbroken packages, for sale or otherwise, or offer to deliver to any other person,'; nor did it 'sell or offer for sale in the district of Columbia or the territory of the United States.'
>
> It seems clear that the transportation of this liquid was solely to the bottles made in Wheeling instead of the transportation of the bottles from Wheeling to the

liquid manufactured in Detroit, and that it was so bottled in Wheeling and properly branded before any sale or disposition of it was attempted."

In the same case the Circuit Court of Appeals in affirming the decision said in part:

"Under the facts disclosed by the record, we conclude that the court below properly found that even if there was probable cause for making the seizure and filing the libel, the evidence made it plainly appear that the appellees shipped the casks as its own product, made by its own agents, from the laboratory of said agents; that the casks of extracts were not intended for sale as shipped, but were to be, at the warehouse of the merchant, bottled and labeled as the law required before being offered for sale. No attempt to evade the law, either directly, indirectly or by substitute, has been shown; it appearing that the manufacturer had simply transferred from one point to another the product he was manufacturing, for the purpose of completing the preparation of same for the market."

In the case of *Stephens Co.,* above cited, the court said in part:

"The court held that the word 'package' as used in the Act (Food & Drug Act) means the package which passed into possession of the public or the real consumer; and that the words 'original unbroken package' relate to the package in the form in which it is received by the vendee or consignee. We agree with Judge Sater (upon this and another question) and so must affirm the judgment."

In the *Hipolite case,* above cited, in distinguishing between the *Danderine Co. case,* in the case then being cited the court said:

> "It may well be considered that there is no analogy between an article in the hands of its owner, or moved from one place to another by him, to be used in the manufacture of articles subject to the Statute, and to be branded in compliance therewith and an adulterated article itself subject to sale and intended to be used as adulterated in controvention of the purposes of the Statute."

The Circuit Court of Appeals has cited the case of *Strong, Cobb & Co.* v. *United States,* 103 Fed. (2d) 671, 673 (C.C.A. 6–1939), as supporting their decision in this case, but it will be noted that the above cited case deals only with the question of adulteration and that a complaint for misbranding was dismissed by the District Court, from which dismissal no appeal was taken.

The case at bar seems clearly to be on all fours with the *Danderine Co. case* above cited. Paul Case was the owner of the goods, that is, of the drugs, caused by him to be manufactured by the Arner Company under a special formula constituting a trade secret to himself, to be shipped by the Arner Company of Buffalo to his plant in Brockton in the bulk package, there to be repackaged and labeled. There can be no question but what title passed to him immediately upon their manufacture because they were under a special formula owned by him, known to him and owned by him and, therefore, were not available for use by anybody else; that title was so recognized as having been passed to him has been shown clearly by the invoice showing that they were shipped F.O.B. from Buffalo. The Arner Company, therefore, was acting throughout as his agent not only in the manufacture of the drugs, but in the shipment of them.

By substituting the names of the two appellants in this case, the language of the court used in *United States* v. *65 Casks Liquid Extract,* above cited, would fit exactly the case at bar and would read as follows:

"It is apparent that the formula of the preparation is a trade secret; that the Arner Company, Inc., were not the owners of this formula, but only the manufacturers, under contract of the owner, Paul Case, and only acted as agent of the owner in directing such shipment to the owner himself of his own property; that such owner did not, 'having so received' such product, either 'deliver, in original unbroken package, for sale or otherwise or offer to deliver to any other person' the same; nor did it 'sell or offer for sale in the District of Columbia or the territory of the United States'."

The decision just cited has not been overruled, it has been sustained in the Circuit Court of Appeals, it has been cited with approval in the Supreme Court in cases subsequently decided and it has apparently been accepted by Congress in the Act passed in 1938, under which the present proceedings are brought. Congress clearly took into account the distinctions emphasized by this decision and recognized it in the definitions above quoted as to the label and labeling appearing upon the package.

If, therefore, there were no other grounds, this libel should be dismissed for the reasons above cited.

II.

SECTION 503 (a) OF THE ACT, (21 U.S.C.A. 353), SPECIALLY EXEMPTS THE BULK PACKAGE HEREIN INVOLVED FROM LABELING UNDER THE PROVISIONS OF THE ACT.

Neither Congress nor the Security Administrator have left any doubt as to the correctness of our position heretofore urged because, by reason of the statute and the regulations promulgated thereunder, this package which is sought to be condemned because misbranded is clearly exempt.

The drugs were manufactured for Paul Case under a special formula owned by Paul Case. They became his goods as soon as process of manufacture began. They were

his goods when they were shipped. They were his goods while in transit; they were his goods when in his plant in the bulk package being repackaged. Nothing can be clearer than that he was the owner of the goods when introduced into interstate commerce. The Arner Company was his agent in manufacturing and in introducing into interstate commerce and was acting under his instructions. The Case goods came squarely within the exemptions cited and nothing more as to labeling could be required than had been done and no libel for condemnation can be sustained, unless it is shown that the retail package on which the label appeared was misbranded. The statute provides as follows:

> "The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at the establishments other than those where originally processed and packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishments."

No statement can be more direct or more mandatory than the above. The mandate is on the Administrator to promulgate regulations which shall exempt from any labeling or packaging requirements of this act drugs and devices of the character attempted to be seized by this libel. The regulations promulgated must be such as will exempt those drugs but the only condition on which the exemption shall fail is the event of their being adulterated or misbranded upon their removal from the processing, labeling or repacking establishment.

There is no allegation in this libel and no facts stated in the Agreed Statement of Facts indicating or alleging that

the drugs or devices were adulterated or misbranded under the provisions of this act upon removal from such processing, labeling or repacking establishment, that is, upon the removal from the establishment of Paul Case. The failure to establish any facts pertaining to adulteration or misbranding upon removal from the processing or repacking establishment is fatal to the maintenance of this libel.

This is not a case where there is any claim that the drugs were in any way adulterated, which would warrant a seizure of them at the time and point where they were seized.

The case, therefore, is clearly distinguished from the *Hippolite Egg Co.* v. *United States*, 220 U.S. 45 and from the *Strong-Cobb Co.* v. *United States*, 103 Fed. (2d) 671, the two cases upon which the Circuit Court of Appeals relied principally in their decision. Their reasoning clearly was in error in this respect.

III.

THE ADMINISTRATOR IS NEITHER AUTHORIZED NOR PERMITTED UNDER THE ACT TO PROMULGATE REGULATIONS WHICH SHALL IMPOSE UPON THE SHIPPER OF BULK PACKAGES OF THE CHARACTER INVOLVED IN THIS LITIGATION ANY BURDENS WHATSOEVER AS TO LABELING REQUIREMENTS.

It was clearly the purpose of Congress to relieve this substantial class of legitimate commercial activities from such burdens because clearly enough the labeling on these bulk packages could not affect the public health for the benefit of which the statute was enacted. The burden of the responsibility to see that the packages were properly labeled was intended to fall upon the operator of the reprocessing and packing and labeling establishment. Any regulations authorized to be promulgated by the Administrator must be directed to the operator of the repackaging establishments. The right to seize goods in bulk package must be conditioned

upon evidence that the operator of the repackaging establishment was misbranding the retail package.

The government contends that exemption can be gained only by complying with the Regulations (2) under 503 (a) and that appellants have not sufficiently complied therewith. The appellants say that they come within the exemptions required by the statute itself and that if any of the regulations promulgated thereunder are within the authority of the Administrator, that they come squarely within the provisions of paragraph (1) of said regulations which purports to exempt "(1) the person who introduced such shipment or delivery into interstate commerce if he is the operator of the establishment where such drug or device is to be processed, labeled or repacked;" As has already been pointed out, Arner Company, Inc., in this case as were Parke Davis in the case of *United States* v. *Knowlton Danderine Co.*, heretofore cited, were but the agents of Paul Case in the manufacture and shipment of the goods of which the libel has been attempted.

The refusal of the Circuit Court of Appeals to recognize this principle of agency is clearly contrary to the force and reasoning of the decision of this Honorable Court.

If Paul Case had gone personally to Buffalo, New York, had personally taken possession of the goods and had personally shipped them to himself at Brockton, Massachusetts, there could then be no question but what the shipment came within paragraph (1) of the Regulation above quoted. Certainly the statute did not contemplate nor require a single individual to be both the shipper and the operator of the reprocessing establishment, nor did it by any stretch of imagination prevent a person who was the owner of a reprocessing or packaging establishment from acting by agents or employees in the shipment of such bulk packages in interstate commerce. To place such construction on the statute, or to permit the issuance of regulations which would enable such a construction to be placed upon the statute,

would be placing an unnecessary burden upon legitimate commercial operations and would be providing no corresponding benefit to the public for whose health these statutes were passed.

If Regulation (1) would serve to exempt Paul Case if he in person shipped from Buffalo, New York, to himself at Brockton, Massachusetts, the selfsame package which has been seized under this libel, certainly so far as the benefits to the public are concerned no greater harm could come to the public by permitting Paul Case through his agent, the Arner Company, to ship this same package with the same label or lack of label upon it to himself at Brockton, Massachusetts. There is nothing in the language of the statute that could warrant or authorize the Administrator in promulgating regulations which would place any burden on any one other than Paul Case, the owner of the repacking establishment and, therefore, Regulation, paragraph (1) not only must apply to the package which has been seized under this libel, but is as far as the Administrator is authorized to go in the promulgation of regulations.

What the Food & Drug Administration has attempted to do in the regulations issued under Section 503 (a), (221 U.S.C.A. 353) of the statute is to write a new Food & Drug & Cosmetic Act and to impose on parties in the position of the Arner Company, Inc., the responsibility not found in any provisions of the statute as enacted by Congress.

On this ground, if on no other, therefore, the libel should be dismissed and the decision of the Circuit Court of Appeals should be reversed as contrary to the reasoning of the statute and the decisions.

IV.

THE GUARANTEE OF THE OPERATOR OF THE REPACKAGING ESTABLISHMENT GIVEN TO THE SHIPPER OF THE BULK PACKAGE IN THE CASE AT BAR, THAT THE DRUGS ARE NOT ADULTURATED NOR MISBRANDED WITHIN THE MEANING OF THE FOOD & DRUG ACT, CONSTITUTES A SUFFICIENT COMPLIANCE WITH ANY REGULATION WHICH THE STATUTE PERMITTED OR REQUIRED TO BE PROMULGATED UNDER THE PROVISIONS OF THE STATUTE.

In the first instance it must be pointed out that the guarantee in the case at bar (Exhibit "C", R., p. 15) complies exactly with the guarantee required under Section 303 (c) (2), which exempts a person from liability for having violated Section 301 (a) (d), "If he establishes a guarantee or undertaking signed by, and containing the name and address of the person residing in the United States from whom he received in good faith the article, to the effect, in case of alleged violation of Section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, etc." The act prohibited under Section 301 (a) is "the introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded."

This is the exact ground on which the libel in the case at bar is founded. The guarantee set forth in the record (p. 15) is in the exact language of this statute. It is, therefore, clearly obvious that if, under any view of the statute, the Arner Company, Inc., can be said to be the person who introduced or delivered for introduction into interstate commerce the drugs in question, then the statute itself required the Arner Company to obtain a guarantee in the exact language in which they did obtain it in order to be exempt from criminal prosecution for violation of the statute.

If the contention of the government with reference to the effect of the requirements of the regulation, paragraph (2) under Section 503 (a) is well founded, then it becomes perfectly clear that in the case at bar the Arner Company, Inc., must obtain two separate guarantees from Paul Case, the one exactly as that company did obtain to meet the requirements of Section 301 paragraph (2) and the other to attempt to meet the requirements of regulation, paragraph (2) under Section 503 (a). This second guarantee would in effect require setting forth in the guarantee itself of the exact contents of the retail label to be placed upon the retail package by Paul Case.

The first form of guarantee would have to be obtained to prevent the criminal prosecution; the second form of guarantee would have to be obtained to prevent the seizure under libel; both to be founded on exactly the same shipment for introduction into interstate commerce.

There is certainly nothing in the language of the statute, Section 503 (a), which requires the Administrator or even permits the Administrator to impose the additional burden upon the shipper, in this case the Arner Company, Inc., of securing a second guarantee other than the one which is specifically required under the language of the statute, Section 303, and in the absence of language in the statute itself which would specifically require a second guarantee in the form prescribed by the regulations quoted, it must be presumed that Congress did not intend to place upon the shipper of the bulk package this additional burden especially where the clear intent of Congress as expressed in the language of the statute heretofore quoted, was to relieve from unnecessary burden the legitimate shipping in interstate commerce of drugs in bulk packages not designed for consumption but for processing, labeling and repacking.

Furthermore, Section 503 (a) directs the Administrator to promulgate regulations which shall exempt from the label-

ing requirements packages such as the one in the case at bar, the only condition of which regulation shall be that they shall not be misbranded nor adulterated on removal from the processing, labeling or repacking establishment. The guarantee obtained in the case at bar (R., p. 15) is a full compliance with any reasonable regulation that could be issued thereunder because it is in express language a guarantee by the operator of the repackaging establishment that the goods are not adulterated or misbranded under the provisions of the statute; in other words, it is a guarantee that the goods when repacked will meet all the labeling requirements of the statute, which means that the label will contain all of the language which the statute requires. No more direct compliance with the statute could be expected or demanded.

On this ground, therefore, if on no other, judgment of the Circuit Court of Appeals should be reversed and the case remanded for the dismissal of the libel.

V.

THE REGULATIONS ESTABLISHED BY THE ADMINISTRATOR SO FAR AS THEY MAY BE HELD TO APPLY TO THE BULK PACKAGE HEREIN INVOLVED EXCEED THE POWER GRANTED UNDER THE STATUTE AND THE INTENT OF CONGRESS IN PASSING SAID STATUTE AND ARE WHOLLY UNWARRANTED AND UNNECESSARY IN APPLYING TO THE CASE AT BAR.

The generally well established proposition of law is as follows:

> "When a subject has been fully regulated by statute an administrative board cannot further regulate it by the adoption of a regulation which is repugnant to the statute. *Commonwealth* v. *McFarlane*, 257 Mass. 530, 531. *Commonwealth* v. *Baronas*, 285 Mass. 321, 322. *Bordgard* v. *Department of Public Works*, 298 Mass.

417. *Commonwealth* v. *Johnson Wholesale Perfume Co., Inc.*, 304 Mass. 452. *Miller* v. *United States*, 294 U.S. 435."

Section 503 (a), (21 U.S.C.A. 353) is as follows:

> "The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirements of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed and packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling or repacking establishments."

This section is mandatory upon the Administrator. He must promulgate regulations, the regulations must exempt from the labeling and packaging requirements of the act all drugs or devices to be processed in substantial quantities in other establishments on one condition only and that is, "that they are not adulterated or misbranded upon the removal from the latter establishments."

The plain unequivocal language of the statute requires the Administrator to exempt from the labeling requirements those drugs designed to be repacked in other establishments unless the labeling at the repacking establishments is in violation of the statute.

The regulations to be issued by the Administrator can apply only to the procedure by which the exemptions may be determined; they cannot enlarge or diminish the class of drugs to be exempted, they cannot increase or decrease the conditions under which the exemptions may be of no avail.

Such attempts would be attempts to deal with the substantive and not the procedural provisions of the law.

The regulations promulgated by the Administrator on the alleged authority of this act far exceed the actual authority granted by the act. The regulations, so far as it is claimed that they affect the appellants in the case at bar, amount to legislation and not regulation at all.

First: The regulation purports to limit the classes entitled to its exemption (1) to the person who introduced into interstate commerce, provided he shall be the same person who repacks, and (2) that if the person who introduced into interstate commerce is not the same person who repacks, then certain agreements shall be obtained from the person who repacks or the original bulk package must contain and comply with the requirements of the statute. The regulations thus applied might well exclude from interstate commerce large numbers of bulk packages in which are contents to be repackaged and labeled and about which there is no complaint of repackaging or labeling, either by reason of misbranding or adulteration of goods, in the packages to be distributed to the consumer. This would very materially reduce the number of persons who, under the broad sweep of the statute, would be entitled to exemption.

The statute says that the regulation shall exempt every drug shipped in interstate commerce in accordance with the practice of the trade.

The regulation purports to exempt only that class of drugs whose shippers comply with certain additional requirements not imposed by the statute.

The Supreme Court has said in *Miller* v. *United States*, 294 U.S. 435, 440:

> "It (the administrative regulation) is invalid because not within the authority conferred by the Statute upon the Director (or his successors, the Administrator) to make regulations to carry out the purposes of the Act. It is not, in the sense of the Statute, a regula-

tion at all, but legislation. The effect of the Statute in force at that time, and the time of the adoption of the so-called regulations, is that in respect of compensation allowances, loss of a hand and an eye shall be deemed total permanent disability as a matter of law.

There being no such provision with respect to cases of insurance, the question whether a loss of that character or of any other specific disability constitutes total permanent disability is left to be determined as a matter of fact. The vice of the regulation, therefore, is that it assumes to convert what, in the view of the Statute, is a question of fact requiring proof, into a conclusive presumption which dispenses with proof and precludes dispute. This is beyond administrative power. The only authority conferred by the Statute is to make regulations to carry out the purposes of the Act and not to amend it. *U. S.* v. *200 Barrels of Whiskey*, 95 U.S. 571, 576. *Morrill* v. *Jones*, 106 U.S. 466, 467. *U. S.* v. *Grimaud*, 220 U.S. 506, 517. *Campbell* v. *Galeno Chemical Co.*, 281 U.S. 599, 610."

The case at bar is a clear illustration of the legislative effect of the so-called regulations of the Administrator. On the record the drugs seized were in accordance with the practice of the trade to be processed, labeled or repacked in substantial quantities at an establishment other than the one where they were originally processed. There is no allegation of misbranding of the retail package and it must be conceded on the record that the drugs were not misbranded under the provisions of the act on removal from such processing, labeling or repackaging establishment, for in fact when they were seized they were still in the bulk package and had not been repacked.

Clearly they were the class of drugs which the statute says the regulations must exempt and yet so-called regula-

tions deprive these very drugs from the exemption which the statute specifically requires that they shall have.

The statute makes the condition upon which the exemption shall fail a question of fact as to whether the drugs, when repacked, are in fact misbranded, the regulation attempts to make this a question of law based on whether a specific form of agreement is obtained in advance between the shipper and repacker.

Clearly, under every established principle of law, the regulations issued by the Administrator affecting the case at bar are invalid and, therefore, inoperative.

It is further reiterated, as has been pointed out under Point IV, heretofore, that the regulation in question exceeds the statute in that it requires guarantee from the person who introduced the goods into interstate commerce, an additional and second guarantee more extensive in its scope than the guarantee required to exempt the same shipper and the same person who introduced into interstate commerce from criminal prosecution for the introduction of any misbranded package into interstate commerce.

There is no contention on the part of the appellants that the shipment in question was not a shipment in interstate commerce, and did not come under the operation of the act because of the fact that it was not in interstate commerce and anything in the opinion of the Circuit Court of Appeals indicating any such contention on the part of the appellants is without support in the record.

Putting the matter succinctly from the standpoint of the appellant Paul Case, the government is attempting to condemn drugs owned by him, and seized while in his warehouse, and while he was actually in the process of repacking and labeling as required by the statute. Why should Paul Case lose his goods when he has violated no statute?

For the reasons above given, if for no others, the case should be remanded to the Circuit Court of Appeals with instructions to dismiss the libel.

CONCLUSION.

Your petitioners respectfully submit, therefore, that this Honorable Court should grant Certiorari in this case.

Respectfully submitted,

CLINTON ROBB,
HERBERT S. AVERY,
Solicitors for Appellants.

No. 801

In the Supreme Court of the United States

OCTOBER TERM, 1944

ARNER COMPANY, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE THIRD CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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605729—44——1

In the Supreme Court of the United States

OCTOBER TERM, 1944

No. 301

ARNER COMPANY, INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES CIRCUIT COURT OF APPEALS FOR THE FIRST CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the circuit court of appeals (R. 20–33) is reported at 142 F. (2d) 730. The memorandum of decision of the district court appears at pages 8–9 of the Record.

JURISDICTION

The judgment of the circuit court of appeals was entered May 4, 1944 (R. 33). The petition for a writ of certiorari was filed July 29, 1944. The jurisdiction of this Court is invoked under Section 240 (a) of the Judicial Code, as amended by the Act of February 13, 1925.

QUESTIONS PRESENTED

1. Whether shipments in bulk of drugs intended to be processed and labeled before sale to the consumer are *ipso facto* exempt from the labeling requirements of the Federal Food, Drug, and Cosmetic Act.

2. Whether the Federal Security Administrator was authorized to promulgate a regulation requiring as a condition for the exemption of bulk shipments from the labeling requirements of the Act, that the shipper and the processor enter into a written agreement containing specifications for the processing, labeling, or repacking of the final product.

3. Whether a manufacturing agent who prepares drugs in accordance with a formula owned by the processor and sends such drugs to the processor in bulk form is a person introducing the bulk shipment into interstate commerce.

STATUTE AND REGULATIONS INVOLVED

The pertinent provisions of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 U. S. C. 301 ff, are as follows:

> SEC. 201 (21 U. S. C. 321). For the purposes of this Act—
>
> * * * * *
>
> (k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or

other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

* * * * *

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

* * * * *

SEC. 304 (a) (21 U. S. C. 334 (a)). Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *.

* * * * *

SEC. 502 (21 U. S. C. 352). A drug or device shall be deemed to be misbranded—

* * * * *

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such

there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein * * *.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided,* That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

* * * * *

SEC. 503 (a) (21 U. S. C. 353 (a)). The Administrator is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of

this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

The pertinent regulations promulgated by the Administrator pursuant to Section 503 (a) (21 C. F. R. 1938 Supp., 2.107) are as follows:

(a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the Act if—

(1) the person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) in case such person is not such operator, such shipment or delivery is made to

such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the Act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

STATEMENT

A libel was filed in the United States District Court for the District of Massachusetts seeking the condemnation of certain drugs shipped by Arner Company, Inc., from Buffalo, New York, to Paul Case at Brockton, Massachusetts, on the ground that the drugs were misbranded within the meaning of the Federal Food, Drug and Cosmetic Act in that the labels failed to bear the common names of the active ingredients, and contained no directions for use of the drugs and no warnings against use under conditions that might be dangerous to

health (R. 2–3). Petitioners filed separate answers to the libel (R. 3–5). The cause was heard on the pleadings and on an agreed statement of facts (R. 10–11), and on April 6, 1943, the district court entered a decree of forfeiture (R. 7). On appeal, the decree of the district court was affirmed (R. 33).

The material facts, as set forth in the agreed statement, are as follows:

The drugs seized under the libel consisted of a drum containing about 40,000 tablets which had been manufactured in Buffalo, New York, by petitioner Arner Company, Inc., for petitioner Paul Case under a special formula owned by Case. They had been shipped f. o. b. Buffalo by Arner to Case at Brockton, Massachusetts. At the time they were seized they were in Case's establishment in the bulk package in which they had been shipped (R. 10–11, 14). The drum was labeled "Special Formula Tablets No. 2 * * * —The product contained herein must be packaged and labeled at point of destination before sale" (R. 13). On April 28, 1939, prior to the shipment in question, Case had delivered to Arner a letter guaranteeing "that each shipment or other delivery hereinafter made of the drug known or designed as my Formula No. 1 and Formula No. 2, is not adulterated or misbranded, as of the date of such shipment or delivery, within the meaning of the Federal Food, Drug and Cosmetic

Act, and is not an article which may not under the provisions of Section 505 [21 U. S. C. 355] of the Act, be introduced into commerce" (R. 10, 15). Arner was not the operator of the establishment at which the drugs were to be repackaged and labeled for the retail trade (R. 10).

ARGUMENT

1. Petitioners contend (Pet. 8, 9, 13–23) that under the definition of "label" set forth in Section 201 (k) of the Act (*supra*, pp. 2–3), shipments in bulk of drugs which are intended for repackaging and labeling before they reach the ultimate consumer need not under any circumstances be labeled in compliance with the requirements of Section 502. However, "label" is broadly defined in Section 201 (k) as "a display of written, printed, or graphic matter upon *the immediate container of any article.*" (Italics supplied.) No distinction is made between articles in bulk and articles packed for retail sale. In addition, "labeling" is defined in Section 201 (m) (*supra*, p. 3) as including "all labels and other written, printed, or graphic matter (1) upon *any* article or *any* of its containers or wrappers * * *." (Italics supplied.) The second clause of Section 201 (k), specifically referring to retail packages and requiring an additional statement on the outside container or wrapper, as well as on the immediate container, is obviously an extension, and not a limitation, of the

general definition. That Congress intended that bulk shipments, unless exempted, shall be labeled in compliance with the Act is shown by the fact that it found it necessary to direct the Administrator to promulgate regulations providing for the exemption from the labeling requirements of drugs and devices which are, in accordance with the practice of the trade, to be processed, repacked, or labeled at establishments other than those where they are originally processed or packed (Sec. 503 (a), *supra,* pp. 4–5). As the court below pointed out (R. 23), if bulk shipments were not subjected to the labeling requirements under the general definition, there would have been no need for the exemption provision.

McDermott v. *Wisconsin*, 228 U. S. 115, cited by petitioners (Pet. 14), which defined the term "package" as used in the Federal Food and Drugs Act of 1906 (34 Stat. 768) as "the immediate container of the article which is intended for consumption by the public" (228 U. S. at 130), is not apposite. In that case the principal issue concerned the validity of a state statute regulating labels on retail packages in view of its possible conflict with the Federal act, and the resolution of that issue turned on the question whether the requirements of the 1906 act extended to labels on the immediate containers of retail packages or were confined in their application to the outside wrapping or box in which such packages were shipped. Unlike the present statute, the 1906

act contained no definitions of "label" and "labeling" and no provision for the exemption of bulk shipments intended to be repacked and labeled. This Court held that that act covered retail packages; that to limit "the requirements of the act as to adulteration and misbranding simply to the outside wrapping or box containing the packages intended to be purchased by the consumer, so that the importer, by removing and destroying such covering, could prevent the operation of the law on the imported article yet unsold, would render the act nugatory and its provisions wholly inadequate to accomplish the purposes for which it was passed" (228 U. S. at 130–131).[1] The Court did not have before it and did not determine the question whether labeling was required on a bulk shipment which contained no retail packages. Hence, the decision and language of the Court in the *McDermott* case furnish no support for petitioners' contention that the labeling requirements of the present statute do not extend to such shipments.[2]

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[1] *Dr. J. L. Stephens Co.* v. *United States*, 203 Fed. 817 (C. C. A. 6), also cited by petitioners (Pet. 21), involved a similar question as to the labeling under the 1906 act of retail packages.

[2] The decision in *United States* v. *Knowlton Danderine Co.*, 175 Fed. 1022 (C. C. A. 4), relied upon by petitioners as presenting a conflict with the decision below (Pet. 9, 20–21, 26), turned upon different considerations than those urged by petitioners here. The lower court had held in that case that a shipment of drugs from the manufacturing agent to the owner was not a shipment in interstate commerce. *United*

2. Petitioners also contend (Pet. 23–26, 28–34) that under Section 503 (a) of the present act, which directs the Administrator to promulgate regulations exempting from the labeling requirements of the act drugs which are to be processed, labeled, or repacked at establishments other than those where originally processed on condition that such drugs are not adulterated or misbranded

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States v. *Sixty-five Casks Liquid Extract*, 170 Fed. 449 (N. D. W. Va.). In affirming the order dismissing the libel, the circuit court of appeals held that the casks were not subject to the 1906 act because they "were not intended for sale as shipped." 175 Fed. at 1022. Section 10 of the 1906 act (34 Stat. 771) provided for the seizure of adulterated or misbranded articles "being transported from one State * * * to another for sale," and there was thus some justification for a holding that goods transported for further processing were not transported for sale. This Court held, however, in *Hippolite Egg Co.* v. *United States*, 220 U. S. 45, that adulterated foods shipped by the owner from one state to another for further processing were subject to the 1906 act (see also *Strong, Cobb & Co.* v. *United States*, 103 F. (2d) 671, 673 (C. C. A. 6), *Philadelphia Pickling Co.* v. *United States*, 202 Fed. 150 (C. C. A. 3)), and its holding in this respect was interpreted as overruling the *Knowlton* decision in respect of misbranded goods as well. *United States* v. *426 Bags of Economy Special Hog Feed*, 276 Fed. 34 (W. D. Mich.). But regardless of the authoritativeness of the *Knowlton* case under the 1906 act, it has no controlling force here, for Section 304 of the present act (*supra*, p. 3) omits the words "for sale" and provides for the seizure of any misbranded or adulterated article "when introduced into or while in interstate commerce." Petitioners admit (Pet. 34) that the shipment here involved was a shipment in interstate commerce. Cf. *Santa Cruz Fruit Packing Co.* v. *National Labor Relations Board*, 303 U. S. 453, 463; *Barnes* v. *United States*, 142 F. (2d) 648, 650 (C. C. A. 9).

upon removal from such repacking establishments (*supra*, pp. 4–5), regulations issued by the Administrator must be directed to the operator of the repacking establishment and must affirmatively provide for the exemption of bulk shipments subject only to the condition that the drugs be not misbranded when removed from such establishment for sale to the public. There is no warrant for such a narrow construction of Section 503 (a). The section clearly expresses an intention to relieve bulk shipments from the labeling requirements only under conditions which will insure that the drugs are properly labeled when sold to the public. The fact that the ultimate purpose is to protect the consumer does not, however, preclude reasonable regulations directed to the shipper, as well as the processor, which are designed to further that object. The regulations promulgated by the Administrator are valid if they fulfill the purpose of the statute, *United States* v. *Antikamnia Co.*, 231 U. S. 654, 667, and his judgment as to the conditions which will facilitate that purpose are entitled to great weight. Cf. *Security Administrator* v. *Quaker Oats Co.*, 318 U. S. 218, 228.

Paragraph (a) (2) of the regulations here involved, which requires, as a condition for the exemption of bulk shipments, that the shipper and the processor enter into a written agreement containing specifications for the labeling of the drugs as sold to the consumer (*supra*, pp. 5–6),

is clearly designed to effectuate not only the objectives of the statute as a whole, but also the particular condition set forth in Section 503 (a) that the finished product shall comply with the statutory standards. The regulation merely requires both parties who are responsible for the finished product to state in writing that they propose to do what the act requires them to do, and to state their purpose in terms explicit enough to show good faith. The person who manufactures and ships the drugs in bulk knows what the product contains and how it should be labeled. He may label the bulk shipment itself, or he may avoid the labeling requirements by agreeing with the processor as to the correct labeling. In either event he would be indicating, when he uses the instrumentalities of interstate commerce for the shipment of the drugs, that they are to be properly labeled when sold to the ultimate consumer.[3] Moreover, as the court below pointed out (R. 27–28, 32), the requirement that bulk shipments be properly labeled or that the specifications for labeling be specifically set forth in a written agreement facilitates the administration of the act in

[3] Petitioners' contention (Pet. 28–29) that the regulation is invalid because it imposed a requirement different from that set forth in Section 303 (c) (2), 21 U. S. C. 333 (c), exempting consignees from criminal prosecution if they receive a guarantee from the shipper, is specious. Section 303 (c) (2) applies to the person who receives the drugs from another, not to the person who first ships the drugs. Cf. *United States* v. *Dotterweich*, 320 U. S. 277.

that the federal authorities may ascertain at an early stage whether drugs shipped in bulk form will actually meet the statutory standards when repacked and labeled for sale to the consumer.

3. There is no merit in petitioner's further contention (Pet. 26–27) that, since title to the drugs passed to petitioner Case upon their shipment from New York to Massachusetts, the shipment is covered by paragraph (a) (1) of the regulations, which exempts from the labeling requirements of the act drugs introduced into interstate commerce by a shipper who is also the operator of the establishment at which the drugs are to be repacked or labeled (*supra,* p. 5). Arner Company, which admittedly is not the operator of the establishment at which the drugs were to be repacked, actually shipped the drugs, and was therefore the "person" who introduced the shipment into interstate commerce. The obvious purpose of paragraph (a) (1) of the regulations is to distinguish between situations where the person who manufactures and ships the bulk article is the one who processes it for the retail trade, and situations where one person ships the bulk product and another processes it. In the first instance one person is responsible for the whole operation; in the other there is the possibility that each of the two persons involved will try to shift responsibility to the other, a situation which paragraph (a) (2) of the regulations is intended to prevent. It may be, as petitioners contend (Pet.

27), that the shipment would have been within the scope of paragraph (a) (1) if Case had himself shipped the bulk package from Buffalo to Brockton but, in that event Arner Company would not have been using the instrumentalities of interstate commerce and therefore would not have come within the purview of the act. The fact that the act does not apply to manufacturers who do not send their products through interstate commerce does not prevent the Administrator from issuing reasonable regulations to cover situations where they do. The technicalities of the law of sales as to the passage of title do not alter the interstate character of the transaction and cannot be used to avoid responsibility under the act. *Barnes* v. *United States,* 142 F. (2d) 648, 650 (C. C. A. 9).

CONCLUSION

The decision below is correct and presents no real conflict of decisions. We therefore respectfully submit that the petition for a writ of certiorari should be denied.

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